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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,461	03/27/2001	Benjamin D. Silverman	YOR920000779US2	1831

7590 06/08/2004  
Ryan, Mason & Lewis, LLP  
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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/818,461

**Applicant(s)**

SILVERMAN, BENJAMIN D.

**Examiner**

Michael Borin

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 4,7-21,32,36 and 38-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,22-24,26,27,33-35,37,38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Status of Claims***

1. Response filed 04/01/2004 is acknowledged.

Claims 1-43 are pending. Applicant incorrectly indicates that claims 1-3,5,6,22-24,26,27,33-35,37,38 are pending. Claims 4,7-21,38-32,36,39-43 remain pending and withdrawn from consideration.

Rejections not reiterated from previous Office actions are hereby withdrawn. The following rejections constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 112, second paragraph***

2. Claims 1-3,5,6,22-24,26,27,33-35,37,38 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1,22,33, and claims dependent therefrom, recite the step of determining hydrophobicity distribution of a protein, which is vague and indefinite. It is not clear whether, the distribution of protein addressed in the claim is in some physical environment, virtual environment, or, as it seems from the specification, is not a distribution of protein at all, but distribution of hydrophobicity throughout the given protein molecule. Please clarify.

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Response to arguments

Applicant explains that the hydrophobicity distribution is determined from the spatial distribution of amino acid residues. This may explain the term hydrophobicity distribution of amino acid residues in protein, but not the "hydrophobicity distribution of a protein" as used in the claims. Further, the section in specification addressed by applicant, describes values of hydrophobicity of amino acid residues lying within certain surface, not "hydrophobicity distribution of a protein".

***Claim Rejections - 35 U.S.C. § 101***

3. Claims 1-3,5,6 remain rejected under 35 USC 101 because the claimed invention is drawn to non-statutory subject matter.

Examiner maintains that the listed instant claims are drawn to computation or manipulation of data or abstract information and as such is non-statutory subject matter due to being drawn to a non-tangible mathematical invention. No production or change in actual material is seen in the instant claims and thus it is deemed non-statutory subject matter.

***Claim Rejections - 35 USC § 112, first paragraph***

4. Claims 1-3,5,6,22-24,26,27,33-35,37,38 remain rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for a

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computer-driven computational method made on a protein modeled in virtual environment, does not reasonably provide enablement for a method of profiling proteins by physically changing protein's hydrophobicity in a real environment.

Applicant correctly reflects Examiner position that the claims seem to encompass not only computer-generated shifting in hydrophobicity but also physical processes. Examiner interprets claims as broadly as their term reasonably allow.

***Claim Rejections - 35 USC § 102 and 103***

5. Claim 1 remains rejected under 35 U.S.C. 102(b) as anticipated by Bar-Or et al (Database CaPlus, DN 103:84898. Archives of Microbiology, 1985, 142(1), pages 21-27). The rejection is maintained for the reasons of record.

Applicant argues that the reference is different as it teaches changing cell-surface properties. However, as addressed in the previous rejection, Examiner interprets the claim as encompassing physical, not only computer-generated, changes in hydrophobicity. To this end, the referenced method includes initial evaluation of hydrophobicity, which reads on instantly claimed step of "determining a hydrophobicity distribution" , and a step of treatment of cell surface which clearly shifts hydrophobicity distribution of a protein (e.g., as a result of treatment with a proteolytic agent).

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6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

June 3, 2004

MICHAEL BORIN, PH.D  
PRIMARY EXAMINER

